APR - 3 2001

K010074

510(k) Summary of Safety and Effectiveness

Device Name	Model 455GE Phased Array Wrist Coil
Applicability	Compatible with GE Signa 1.5T MR systems operating at 4.X – LX software levels and the CV/i system
Reason for 510(k)	New device
Classification Name	Magnetic Resonance Diagnostic Device
Device Classification Panel	Radiology
Device Classification Number	892.1000
Product Code	90LNH
Common Name	Magnetic Resonance Specialty Coil
Proprietary Name	Model 455GE Phased Array Wrist Coil
Establishment Registration Number	2183683
Address of MFG Facility	IGC-Medical Advances Inc. 10437 Innovation Drive Milwaukee, WI 53226
Point of Contact	Michael Leigh Manager, Regulatory Affairs and Quality Assurance (414) 258-3808 Ext. 206
Classification	Class II
Intended Uses	
Diagnostic Uses	Complete imaging of the wrist or hand and imaging of the distal phalanges.
Anatomic Regions	The coil will accommodate 95% of the general population, from the area of the distal end of the 3rd metacarpal to 3 cm above the distal end of the radius/ulna.

Standards

Performance Standards	None Established under Section 514	
Voluntary Safety Standards	UL 2601-1	Medical Electrical Equipment, Part I: General Requirements for Safety
	UL 94	Tests for Flammability of Plastic Materials
	IEC 601-1	General Safety Requirements for Medical Electrical Equipment

Overview

The Radiology Devices Panel considered potential concerns regarding the safe and effective operation of Magnetic Resonance Diagnostic Devices when they recommended reclassification to Class II on July 27, 1987. After reclassification, the FDA's Center for Devices and Radiological Health (CDRH) released a draft guidance document for the content and review of Magnetic Resonance Diagnostic Device premarket notification submissions that offered clarification of these concerns. Due to considerable technological advances in MRDDs, CDRH issued an updated guidance document on November 14, 1998. The following is a summary of the information contained within this premarket notification that addresses these concerns:

The GE Signa 1.5T MRI system operated with the Medical Advances Phased Array Wrist Coil is substantially equivalent to the same system operated with the legally marketed predicate device listed in section 4.0, within the Class II definition of Magnetic Resonance Diagnostic Device with respect to the safety parameter action levels:

Safety Parameters

Maximum Static Magnetic Field:	No change
Rate of Magnetic Field Strength Change:	No change
RF Power Deposition:	No change
Acoustic Noise Levels:	No change

Imaging Performance Parameters

Specification Volume:	No change
Signal-to-Noise Ratio:	No change
Image Uniformity:	No change
Geometric Distortion:	No change
Slice Thickness and Gap:	No change
High Contrast Spatial Resolution:	No change

General Safety and Effectiveness Concerns

The device contains instructions for use. It includes indications for use, precautions, cautions, contraindications, warnings and quality assurance testing. This information assures safe and effective use of the device.

Substantial Equivalence Summary

The GE Signa 1.5T MRI system operated with the Medical Advances Phased Array Wrist Coil addressed in this PMN has the same intended use and technological characteristics as the same system operated with the identified legally marketed predicate devices. The use of this coil does not affect the GE Signa 1.5T system safety parameter specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 2001

Michael Leigh
Manager, Regulatory Affairs and Quality Assurance
IGC Medical Advances, Inc.
10437 Innovation Dr.
MILWAUKEE WI 53226

Re: K010074
Model 455GE, Phased Array Wrist Coil
Dated: January 8, 2001
Received: January 9, 2001
Regulatory Class: II
21 CFR §892.1000/Procode: 90 MOS

Dear Mr. Leigh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010074

Device Name: Model 455GE-64 Phased Array Wrist Coil

Indications for Use:

Complete imaging of the wrist or hand and imaging of the distal phalanges.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010074